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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,985	02/03/2004	Nancy J. Harper	PC10139B	3565

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,985	HARPER-ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/417,175.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Non-Final Rejection

The Status of Claims :

Claims 1-13 are pending.

Claims 1-13 have been rejected.

DETAILED ACTION

Priority

1. It is noted that this application is a continuation of 09/417,175 filed on 10/11/1999 (U.S. 6,727,283), which claims a benefit of 60/104,024 (10/13/1998).

Drawings

2. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 provides for the use of an essentially nonaqueous, liquid concentrate of sertraline where the claim recites " use of an essentially

nonaqueous ,liquid concentrate of sertraline or a pharmaceutically acceptable salt thereof of claim 1 to prepare an aqueous solution of sertraline", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-13 provide for the use of claim 11 where the claim recites " the use of claim 11 wherein the pharmaceutically acceptable salt of setraline is the hydrochloride salt " or " the use of claim 11 wherein the diluent is selected from the group consisting of water , orange juice, ginger ale, lemon-lime soda and lemonade", but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11-13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 13 of U.S. Patent No. 6,727,283. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6,727,283 discloses a pharmaceutical composition containing an essentially non-aqueous, liquid concentrate solution of sertraline hydrochloride in the followings :

1. A pharmaceutical composition which comprises;
an essentially nonaqueous, filterable, liquid concentrate solution of sertraline hydrochloride for oral administration comprising about 18 mg/ml to about 78 mg/ml of sertraline hydrochloride and ethanol and glycerin in an amount of about 8 to about 50% ethanol by weight in glycerin.

2. The composition of claim 1 wherein the concentrate further comprises one or more flavoring agents and one or more pharmaceutically acceptable preservatives.

3. The composition of claim 2 wherein the flavoring agents are selected from the group consisting of peppermint, spearmint and menthol; and wherein the preservatives are selected from the group consisting of butylhydroxytoluene, butylated hydroxyanisole, propyl gallate, ascorbic acid, ascorbyl palmitate, sodium metabisulfite, sodium bisulfite, sodium thiosulfate, sodium hydroxide, cysteine, ethylenediamine tetraacetic acid or salts thereof, citric acid, triethanolamine, thioglycerol, methylparaben and propylparaben.

4. The composition of claim 3 wherein the flavoring agent is menthol and wherein the preservative is butylhydroxytoluene.

5. The composition of claim 4 wherein each ml of the concentrate comprises about 22.4 mg of sertraline hydrochloride, about 151 mg of ethanol, about 0.50 mg of menthol, about 0.10 mg of butylhydroxytoluene, and about 1011 mg of glycerin.

6. A method of using an essentially nonaqueous, liquid concentrate of sertraline hydrochloride of claim 1 to prepare an aqueous solution of sertraline which comprises diluting the concentrate in an aqueous diluent prior to oral administration.

7. The method of claim 6 wherein the diluent is selected from the group consisting of water, orange juice, ginger ale, lemon-lime soda and lemonade.

13. The pharmaceutical composition of claim 1 comprising about 18 mg/ml to about 30 mg/ml of sertraline hydrochloride and ethanol and glycerin in an amount of about 8 to about 20% ethanol by weight in glycerin.

The instant invention, however, differs from the prior art in that (1s-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine methanesulfonate is claimed; and the claimed concentrate comprises sertraline hydrochloride in amount of 15 to 30 mg/ml instead of 18 mg/ml to 30 mg/ml.

With respect to the (1s-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine methanesulfonate compound, the specification of U.S. Patent No. 6,727,283 discloses the claimed compound (see col. 4 ,lines 22-25).

Furthermore, regarding the difference in the concentrate of sertraline hydrochloride, the specification of U.S. Patent No. 6,727,283 also teaches that the concentrate of sertraline hydrochloride is in an amount of 15 to 30 mg/ml (see col. 3 ,lines 53-54).

Their differences are not related to the patentable difference, but the selective emphasis of the claimed inventions. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to select the claimed compound and the specific range of the sertraline hydrochloride concentrate from the specification in order to emphasize
the critical features of the invention.

Thus, the present invention is not patentably distinct from the U.S. Patent No. 6,727,283.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

II. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

III. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826) and Johnson (EP0768083).

Doogan et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral

pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2).

However, Doogan et al differs from the instant invention in that 8 to 20 % ethanol is in glycerin, the flavoring agent is menthol, the preservative is butylhydroxytoluene, and each ml of the concentrate contains 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, and pharmacologically acceptable anions include methanesulfonate.

Howard et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61).

Concerning the claimed range of ethanol in glycerin, the reference is silent. However, Johnson teaches sertraline and its pharmaceutically acceptable salt (hydrochloride) in dosages ranging from 50 to 200mg /day (see page 4 ,lines 1-2) which may be combined with diluents such as ethanol , glycerin, propylene glycol and various combinations (see page 4 ,lines 23-24); furthermore, with respect to the limitation of a process with respect to ranges of pH, time and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Concentration is well-understood by those of ordinary skill in the art to be a result-effective variable, especially when

attempting to control selectivity of a process. Therefore, the person having an ordinary skill in the art had desired to use an optimum range of ethanol in glycerin, it would have been obvious for the skillful artisan in the art to have obtained the claimed range of ethanol in glycerin by a routine experimentation on the Johnson's ethanol and glycerin so as to form a proper liquid dose.

In reference to the flavoring agent being menthol, the reference is silent. However, Howard et al does teach that oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Furthermore, it is well-known in the art that menthol has been used for masking unpleasant flavors. Therefore, the skillful artisan in the art had desired to develop a unique menthol taste in the oral pharmaceutical composition containing sertraline hydrochloride, it would have been obvious for the skillful artisan in the art to have selected the menthol flavor as the masking agent for the product.

With respect to each ml of the concentrate contained 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, the references are silent. However, the pharmaceutical oral composition can contain various excipients with varied concentrations so as to meet special needs for the patients' use. Therefore, the composition of various known excipients do not have any patentable weight in the instant invention in the absence of unexpected results.

Doogan et al does disclose the pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring

agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2). If elixirs are desired for oral administration , the sertraline may be combined with various flavoring agents (see from col. 2 lines 63-67).

Howard et al discloses expressly the pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58); also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61).

Johnson has pointed out sertraline and its pharmaceutically acceptable salt in dosages ranging from 50 to 200mg /day (see page 4 ,lines 1-2) which may be combined with diluents such as ethanol , glycerin, propylene glycol and various combinations (see page 4 ,lines 23-24).

All the prior art are definitively dealt with the pharmaceutical composition containing sertraline hydrochloride with an overlapping dose; they do describe that the pharmaceutical composition containing sertraline hydrochloride may be combined with various pharmaceutically acceptable inert carrier in the form of syrups and solutions. Therefore, if the skillful artisan in the art had desired to develop the product containing non-aqueous liquid concentrate compositions containing sertraline and methanesulfonate as pharmacologically acceptable anions, it would have been obvious to the skillful artisan in the art to have

motivated to incorporate Howard et al 's methanesulfonate ,along with adding Johnson's ethanol and glycerin, into the Doogan et al pharmaceutical composition containing sertraline because, for oral administration, they do indicate that non-aqueous vehicles can be incorporated in the liquid preparations containing sertraline .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor V. Oh 8/31/04

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